



Billing Code 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft Report on Carcinogens Monograph on Antimony Trioxide; Availability of Document; Request for Comments; Notice of Peer-Review Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) announces a meeting to peer review the Draft Report on Carcinogens (RoC) Monograph on Antimony Trioxide. The Office of the Report on Carcinogens, Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS) prepared the monograph. This peer-review meeting is by webcast only and is open to the public. Registration is requested for oral comment and is required to access the webcast. Information about the meeting and registration is available at <https://ntp.niehs.nih.gov/go/38853>.

DATES:

Meeting: January 24, 2018, 8:30 a.m. to adjournment at approximately 4:00 p.m. Eastern Standard Time (EST). The meeting may end sooner or later than 4:00 p.m. EST.

Document Availability: The draft monograph should be available by November 30, 2017, at <https://ntp.niehs.nih.gov/go/38853>.

Written Public Comment Submissions: Deadline is January 10, 2018.

Registration for Oral Comments: Deadline is January 10, 2018.

Registration to View Webcast: Deadline is January 24, 2018. Registration to view the meeting webcast is required.

ADDRESSES:

Meeting Location: Webcast

Meeting Webpage: The draft monograph, preliminary agenda, registration, and other meeting materials will be available at <https://ntp.niehs.nih.gov/go/38853>.

Webcast: The URL for viewing the peer-review meeting webcast will be provided to registrants.

FOR FURTHER INFORMATION CONTACT: Camden Byrd, ICF, 2635 Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293-1660, Fax: (919) 293-1645, Email: camden.byrd@icf.com.

SUPPLEMENTARY INFORMATION:

Background: The RoC is a congressionally mandated, science-based, public health report that identifies agents, substances, mixtures, or exposures (collectively called “substances”) in our environment that pose a cancer hazard for people in the United States. NTP prepares the RoC on behalf of the Secretary of Health and Human Services. NTP follows an established, four-part process for preparing the RoC (<https://ntp.niehs.nih.gov/pubhealth/roc/process/index.html>). For each substance selected

for review, a draft RoC monograph is prepared that presents (1) information on human exposure to the substance; (2) an assessment of the evidence from cancer studies in humans and experimental animals, mechanisms of carcinogenicity, and other data relevant for evaluating the substance's potential carcinogenicity; and (3) NTP's preliminary RoC listing recommendation. The draft monograph also contains a draft profile that provides NTP's preliminary listing recommendation for the substance and a summary of the scientific evidence considered key to reaching that recommendation.

Antimony trioxide was selected for review following solicitation of public comment, review by the NTP Board of Scientific Counselors on December 14–15, 2016, and approval by the NTP Director (<https://ntp.niehs.nih.gov/go/9741>).

Antimony trioxide is the most commercially significant form of antimony and is a high-production-volume chemical with a production volume exceeding one million pounds per year. Its major industrial use is as a synergist with halogenated flame-retardants in textiles, plastics, and rubber. The main exposures to antimony trioxide are from inhalation of airborne solid dust and for workers in facilities producing or using antimony trioxide. Exposures of the public to antimony trioxide are primarily from environmental exposures secondary to human activities. Antimony trioxide can form in the product life cycle of other antimony compounds, such as during the use of automobile brake containing antimony trisulfate, which can oxidize into antimony trioxide. The draft RoC monograph includes a cancer hazard assessment of antimony trioxide.

Meeting and Registration: The meeting is open to the public with time set aside for oral public comment. Registration to view the webcast is by January 24, 2018, at

<https://ntp.niehs.nih.gov/go/38853>. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Individuals with disabilities who need accommodation to view the webcast should contact Camden Byrd by phone: (919) 293-1660 or email: camden.byrd@icf.com. TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

Meeting Materials: The draft monograph and preliminary agenda will be available on the NTP website at <https://ntp.niehs.nih.gov/go/38853>. The draft monograph should be available by November 30, 2017. Additional information will be posted when available or may be requested in hardcopy, contact Camden Byrd by phone: (919) 293-1660 or email: camden.byrd@icf.com.

Following the meeting, a report of the peer review will be prepared and made available on the NTP website. Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

Request for Comments: NTP invites written and oral public comments on the draft monograph. The deadline for submission of written comments is January 10, 2018, to enable review by the peer-review panel and NTP staff prior to the meeting. Registration to provide oral comments is on or before January 10, 2018, at <https://ntp.niehs.nih.gov/go/38853>. Written public comments and any other correspondence on the draft monograph should be sent to Camden Byrd by email: camden.byrd@icf.com. Persons submitting written comments should include name,

affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website, and the submitter will be identified by name, affiliation, and sponsoring organization (if any).

Guidelines for public comments are available at

https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.

Oral public comment at this meeting is welcome, with time set aside on January 24 for the presentation of oral remarks on the draft monograph. Public comments will be presented by teleconference line. Fifty (50) lines will be available for this call; availability is on a first-come, first-served basis. The lines will be open from 8:30 a.m. until adjournment at approximately 4:00 p.m. EST on January 24, 2018 (meeting may end sooner or later than 4:00 p.m. EST). Oral comments will be received only during the formal public comment periods indicated on the preliminary agenda. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Each organization is allowed one time slot. At least 7 minutes will be allotted to each time slot, and if time permits, the allotment may be extended to 10 minutes at the discretion of the chair. Please note: the time per speaker may be decreased if the number of commenters exceeds the total time allotted for public remarks. If the time per speaker changes, commenters would be notified after January 10, 2018, the deadline to register for oral public comments.

Persons wishing to make an oral presentation are asked to register online at

<https://ntp.niehs.nih.gov/go/38853> by January 10, 2018. If possible, oral public commenters should send a copy of their slides and/or statement or talking points to

Canden Byrd by email: can den.byrd@icf.com by January 10, 2018. Written statements may supplement and may expand the oral presentation.

Background Information on the RoC: Published biennially, each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in previous editions. For each listed substance, the RoC contains a substance profile, which provides information on cancer studies that support the listing—including those in humans and animals and studies on possible mechanisms of action, information about potential sources of exposure to humans, and current Federal regulations to limit exposures. The 14th RoC, the latest edition, was published on November 3, 2016 (available at <https://ntp.niehs.nih.gov/go/roc14>).

Background Information on NTP Peer-Review Panels: NTP panels are technical, scientific advisory bodies established on an “as needed” basis to provide independent scientific peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide their current curriculum vitae to Canden Byrd by email: can den.byrd@icf.com. The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service Act, as amended. The panel is governed

by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: November 1, 2017.

John R. Bucher,

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National Toxicology Program.

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